

**REMARKS**

Claims 1, 2, 5, 7, 8, 10-27, 32, 34 and 36-42 are pending in this application. By this Amendment, claims 21-23 are amended.

Entry of the amendments is proper under 37 CFR §1.116 since the amendments:

(a) place the application in condition for allowance (for the reasons discussed herein); (b) do not raise any new issue requiring further search and/or consideration (since the amendments amplify issues previously discussed throughout prosecution); (c) satisfy a requirement of form asserted in the previous Office Action; and (d) place the application in better form for appeal, should an appeal be necessary. In particular, claims 21 and 23 are merely amended to recite "consists of" as suggested in the Office Action. In addition, claim 22 is merely amended to be in independent form. The amendments are necessary and were not earlier presented because they are made in response to arguments raised in the final rejection. Entry of the amendments is thus respectfully requested.

Applicants appreciate the courtesies shown to Applicants' representative by Examiner Mark Navarro during the June 5, 2003 personal interview and by Examiner Lynette Smith during the August 7, 2003 telephone interview. Applicants' separate record of the substance of the interviews is incorporated into the following remarks.

Applicants also appreciate the indication that claims 1 and 2 are allowed. It is respectfully submitted that all of the claims are allowable for the reasons discussed below.

**I     Enablement Rejection**

Claims 5, 7, 8, 10-27, 32, 34 and 36-40 are rejected under 35 U.S.C. §112, first paragraph, for allegedly not being enabled. Applicants respectfully traverse the rejection.

In rejecting these claims, the Office Action objects to use of "consists essentially of" language rather than "consists of" language. However, the Office Action also refers to Paper Number 25. In Paper Number 25, it is stated that:

Applicant's are asserting that it would be within the skill of the art to use fragments having at least 85% homology to a reference sequence as probe or primer. Applicant's further assert that one of ordinary skill in the art would understand that a fragment having 85% homology to the reference sequence can be successfully hybridized to the reference sequence.

However, the Office Action does not clearly reject the claims based on inclusion of language reciting 85% homology. Therefore, if the claims are rejected based on inclusion of this recitation, it is respectfully requested that this be clarified in an effort to place this application in a better condition for appeal, should an appeal be necessary.

**Claim 27 Does Not Recite The Rejected Language**

With regard to claim 27, it is noted that this claim does not contain "consists essentially of" language or "% homology" language. Therefore, none of the bases for rejection under §112, first paragraph, apply to this claim. Thus, this rejection should clearly be withdrawn with regard to claim 27.

**Claims 21-23 Have Been Amended To Recite "Consists Of"**

Claims 21 and 23 have been amended to delete the term "essentially." In addition, in making claim 22 independent, the "consists of" language of amended claim 21 was used. Thus, claims 21-23 are now directed to the "consists of" language desired by the Examiner. Therefore, with regard to claims 21-23, and claims 24 and 36-38, which depend on one of claims 21-23, this rejection should clearly be withdrawn.

**Claims 5 And 8 Are Also Enabled**

It is respectfully submitted that the rejection should also be withdrawn with regard to the other rejected claims. In particular, it is respectfully submitted that "consists essentially of" language does not render the claims not enabled.

Claims 5 and 8 are directed to probes and primers that "consist essentially of" a sequence, respectively. It is respectfully submitted that probes and primers that consist essentially of the recited sequence are enabled by the present specification. In particular, one

of ordinary skill in the art is well aware that additional matter can be added to a probe or primer without affecting the basic and novel characteristics of that probe or primer. For example, a label can be and is routinely added to a probe without effecting the basic and novel characteristics of the probe, which allows it to identify *Trypanosoma cruzi*. In addition, it is well known in the art that additional nucleotides can be added to one or more ends of a probe or primer without affecting the basic and novel characteristics of that probe or primer.

In the Office Action, it is argued that the phrase "consisting essentially of" will be construed as equivalent to "comprising" since there is allegedly not a clear indication in the specification or claims of what the basic and novel characteristics actually are. It is respectfully submitted that it is clear from the claims and specification that the basic and novel characteristics of the inventions of claims 5 and 8 are clearly the ability of these sequences to hybridize and therefore act as a probe or primer, respectively, for identifying *Trypanosoma cruzi* or amplifying a nucleotide sequence thereof. Thus, "consists essentially of" language does have meaning in the context of claims 5 and 8.

In addition, it is respectfully submitted that even if these claims are construed as having language equivalent to "comprising" language, claims 5 and 8 are still enabled by the present specification. In particular, use of the term "comprising" has consistently been allowed despite the fact that in all technologies it opens the claims to the inclusion of elements that could have a negative impact on the ability of the recited elements to function for their intended purpose. The fact that "comprising" language is open-ended does not create an enablement issue. Instead, based on the present disclosure, one of ordinary skill in the art would have been able to practice the invention without undue experimentation. As noted in the Office Action, if one of ordinary skill in the art chooses to add nucleotides up and/or downstream of the recited sequence, he or she would need to test the ability of the modified sequence to act as a probe or primer. However, such experimentation would have been

considered routine in the art at the time of the present invention. Therefore, claims 5 and 8 and the claims dependent thereon are clearly enabled by the present specification.

### **Conclusion**

Claims 5, 7, 8, 10-27, 32, 34 and 36-40 are clearly enabled by the present specification. Therefore, the enablement rejection under 35 U.S.C. §112, first paragraph, should be reconsidered and withdrawn.

### **II. Written Description Rejection**

Claims 5, 7, 8, 10-27, 32, 34 and 36-40 are rejected under 35 U.S.C. §112, first paragraph, for allegedly lacking written description. Applicants respectfully traverse the rejection.

#### **Claims 21-23 And 27 Do Not Recite "Consists Essentially Of" Language**

In alleging that the rejected claims lack written description, the Office Action merely refers to the "consisting essentially of" language. However, as noted above, claim 27 does not recite "consisting essentially of" language and claims 21-23 have been amended herein such that they no longer recite "consisting essentially of" language. Therefore, with regard to claims 21-23 and 27, as well as claims 24 and 36-38 that depend on one of claims 21-23, the written description rejection should be withdrawn.

#### **The Specification Also Provides Written Description For Claims 5 And 8**

In addition, it is respectfully submitted that the specification clearly provides written description for the invention described in claims 5 and 8. The basis for maintaining this rejection is the argument that the "consisting essentially of" language will be construed as equivalent to "comprising" language. It is respectfully submitted for the reasons discussed above with regard to the enablement rejection that the "consists essentially of" language should not be construed as "comprising" language. However, as with the enablement rejection, even if the "consisting essentially of" language is construed as "comprising"

language, no written description requirement is created. Instead, the specification clearly demonstrates possession of the invention of claims 5 and 8 by including SEQ ID NO: 1, by specifically identifying the portion thereof starting at nucleotide 1232 and ending at nucleotide 2207 thereof, by describing sequences having 85% homology to this sequence, and by specifically describing probes and primers "containing" these sequences. See page 15, line 16. Although the Federal Circuit has held that merely reciting an invention does not necessarily provide written description for that invention, the present specification, which recites SEQ ID NO: 1, clearly provides written description for claims 5 and 8.

### **Conclusion**

The specification clearly provides written description for claims 5, 7, 8, 10-27, 32, 34 and 36-40. Therefore, the written description rejection under 35 U.S.C. §112, first paragraph, should be reconsidered and withdrawn.

### **III. Art Rejection**

Claims 5, 8, 10, 11, 17, 25, 26, 32, 34, 39 and 40 are rejected under 35 U.S.C. §102 over Birkett et al. (hereinafter "Birkett"). Applicants respectfully traverse the rejection.

Birkett describes a random hexamer kit. The Examiner agrees that this kit would not contain every hexamer, noting that "every conceivable sequence of six consecutive nucleotides is not contained within the kit disclosed by Birkett et al." However, the Office Action argues that because the claims only require 85% homology Birkett is being deemed anticipatory.\* However, this is clearly in contrast with inherency law, which has consistently held that to invalidate a claim based on inherency, inherency must be a necessary result and not merely a possible result. The mere fact that a certain thing may result from a given set of circumstances is not enough. In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA

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\* It is further noted that claim 10 recites specific sequences, rather than 85% homology with a specific sequence. The Office Action provides no basis for rejecting this claim under §102.

1981); Ex parte Keith and Turnquest, 154 USPQ 320, 321 (Bd. Pat. Appl. & Int. 1966).

There is no reason to assume that a hexamer having a 100% homology with the recited sequence or even a hexamer having 85% homology with a recited sequence is necessarily present in the random hexamer kit described in Birkett. Therefore, the §102 rejection over Birkett must be withdrawn.

#### **IV. New Matter Rejection**

Claims 41 and 42 are rejected under 35 U.S.C. §112, first paragraph, for allegedly containing new matter. Applicants respectfully traverse the rejection.

The specification clearly describes probes having nucleotides in the range of from 5-100 monomers. In addition, the specification clearly describes primers containing nucleotides in the range of from 5-30 monomers. Thus, the specification clearly also teaches probes and primers of lengths between 5-100 and 5-30, respectively, including probes and primers having a length of at least 7 monomers. See In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) (which held that a claim limitation of "between 30% and 60%" was supported by a specification that included a range of "25%-60%" and specific examples of 36% and 50%).

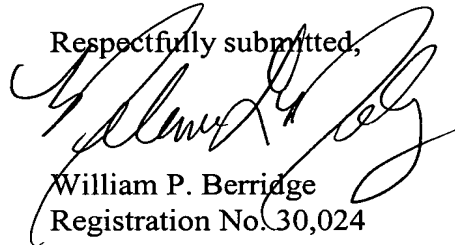
Claims 41 and 42 are clearly supported by the present specification. Therefore, the rejection of these claims under 35 U.S.C. §112, first paragraph, should be reconsidered and withdrawn.

#### **V. Closing**

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1, 2, 5, 7, 8, 10-27, 32, 34 and 36-42 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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